



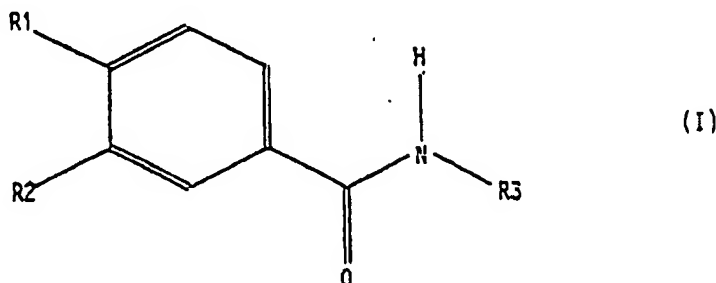
Appendix A

Claim Amendments

This listing of claims will replace all prior versions, and listings, of claims in the application.

1.-37. (Canceled)

38. (Currently Amended) ~~The A~~ process for producing a dosage form ~~as claimed in claim 18~~ for oral administration of a PDE 4 inhibitor, comprising the steps:
(a) producing a mixture of a PDE 4 inhibitor of formula I and one or more pharmaceutical excipients



in which

R1 is difluoromethoxy,

R2 is cyclopropylmethoxy and

R3 is 3,5-dichloropyrid-4-yl,

or a salt of this compound, an N-oxide of the pyridine of this compound or a salt thereof; and

(b) granulating the mixture obtained in (a) with an aqueous solution of polyvinylpyrrolidone;

wherein the dosage form is in tablet or pellet form, wherein said dosage form has

immediate release of the PDE 4 inhibitor.

39. (Previously presented) The process according to claim 38, further comprising:

- (a) drying the granules,
- (b) optionally admixing other pharmaceutical excipients,
- (c) mixing with a release agent and
- (d) compressing in a tablet press.

40. (Previously presented) The process according to claim 38, further comprising processing wet preparations obtained after granulating to pellets.

41. (Previously presented) The process according to claim 38, wherein the granulating takes place in a fluidized bed granulator.

42. (Currently Amended) The process according to claim 38, wherein in step (a) the PDE 4 inhibitor is admixed with ~~either~~ the one or more pharmaceutical excipients in the form of a trituration with a pharmaceutical excipient.

43. (Currently Amended) The process according to claim 42, which trituration is obtained by grinding the PDE 4 inhibitor with a the one or more pharmaceutical excipients.

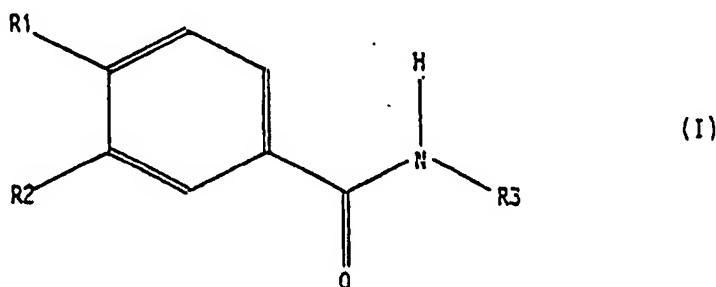
44. (Previously presented) The process according to claim 42, wherein the pharmaceutical excipient is a filler.

45. (Previously presented) The process according to claim 38, comprising granulating a mixture of (a) a PDE 4 inhibitor of formula I, or a trituration of a PDE 4 of formula I with corn starch, (b) corn starch and (c) lactose monohydrate with an aqueous polyvinylpyrrolidone solution to form granules, drying the granules, mixing the granules with a release agent and compressing the granules in a tablet press.

46. (Previously presented) The process according to claim 38, comprising granulating a mixture of (a) a PDE 4 inhibitor of formula I, or a trituration of a PDE 4 of formula I with corn starch, (b) corn starch, (c) microcrystalline cellulose and (d) sodium carboxymethylstarch with an aqueous polyvinylpyrrolidone solution to form granules, drying the granules, mixing the granules with a release agent and compressing the granules in a tablet press.

47. (Currently Amended) A process for producing a dosage form ~~as claimed in claim 18~~ for oral administration of a PDE 4 inhibitor, comprising the steps:

- (a) producing a mixture of pharmaceutical excipients; and
- (b) granulating the mixture obtained in (a) with a suspension of ~~the~~ a PDE 4 inhibitor of formula I in an aqueous solution of PVP



in which

R1 is difluoromethoxy.

R2 is cyclopropylmethoxy and

R3 is 3,5-dichloropyrid-4-yl,

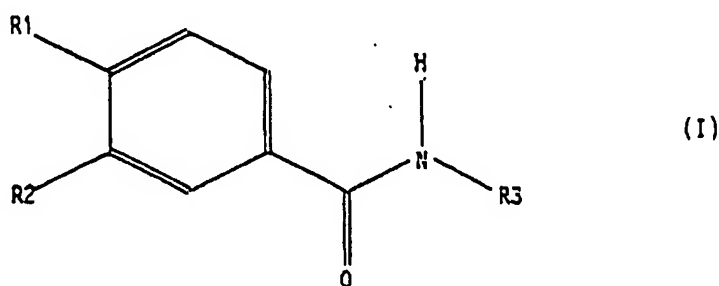
or a salt of this compound, an N-oxide of the pyridine of this compound or a salt thereof;

wherein the dosage form is in tablet or pellet form, wherein said dosage form has immediate release of the PDE 4 inhibitor.

48. (Previously presented) The process according to claim 47, comprising granulating a mixture of corn starch and lactose monohydrate with a suspension of a PDE 4 inhibitor of formula I in an aqueous solution of PVP to form granules, drying the granules, mixing the granules with a release agent and compressing the granules in a tablet press.

49.-52. (Canceled)

53. (Currently Amended) A process for producing a dosage form ~~as claimed in claim 18~~ for oral administration of a PDE 4 inhibitor, comprising the steps: (a) producing an active ingredient preparation in the form of a solid solution in polyvinylpyrrolidone of a PDE 4 inhibitor of formula I,



in which

R1 is difluoromethoxy,

R2 is cyclopropylmethoxy and

R3 is 3,5-dichloropyrid-4-yl,

or a salt of this compound, an N-oxide of the pyridine of this compound or a salt thereof;

(b) producing a mixture of an active ingredient preparation and pharmaceutical excipients and

(c) granulating the mixture obtained in (b) with an aqueous solution of polyvinylpyrrolidone;

wherein the dosage form is in tablet or pellet form, wherein said dosage form has immediate release of the PDE 4 inhibitor.

54. (Previously presented) The process according to claim 53 for producing a dosage form in the form of a tablet, wherein the granules obtained in step (c) are dried, mixed with lubricants or release agents and compressed in a tablet press.

55. (Previously presented) The process according to claim 53 for producing a dosage form in the form of pellets, wherein the wet granules obtained in step (c) are produced by an extruder/spheronizer process to suitable pellets.

56.-64. (Canceled)

65. (Previously presented) The process according to claim 43, wherein the pharmaceutical excipient is a filler.

66.-67. (Canceled)

68. (New) The process according to claim 47, wherein the polyvinylpyrrolidone is selected from the group consisting of polyvinylpyrrolidone of molecular weight 28,000 – 34,000, polyvinylpyrrolidone of molecular weight 44,000 – 54,000 and polyvinylpyrrolidone of molecular weight 1,000,000 – 1,500,000.

69. (New) The process according to claim 47, wherein the PDE 4 inhibitor is N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide (roflumilast).

70. (New) The process according to claim 47, wherein the PDE 4 inhibitor is the N-oxide of the pyridine of the compound of formula I.

71. (New) The process according to claim 69, wherein the dosage form contains from 0.01 mg to 5 mg of roflumilast per dosage unit.

72. (New) The process according to claim 47, wherein the proportion of polyvinylpyrrolidone is from 1 to 5% by weight.

73. (New) The process according to claim 47, wherein the proportion of polyvinylpyrrolidone is from 2 to 3% by weight.

74. (New) The process according to claim 47, where the pharmaceutical excipients are excipients selected from the group consisting of fillers, additional binders, tablet

disintegrants, lubricants, release agents, flavouring substances, buffer substances, preservatives, coloring substances and emulsifiers.

75. (New) The process according to claim 47, wherein the proportion of all binders present is from 0.5 to 20% by weight.

76. (New) The process according to claim 74, which is a tablet and wherein the proportion of filler is from 40 to 99% by weight.

77. (New) The process according to claim 74, wherein the filler is selected from the group consisting of sugar alcohols, starches, saccharides and mixtures thereof.

78. (New) The process according to claim 77, wherein the filler is selected from the group consisting of corn starch, microcrystalline cellulose, lactose and mixtures thereof.

79. (New) The process according to claim 74, wherein the lubricant or release agent is selected from the group consisting of sodium stearyl fumarate, magnesium stearate, calcium stearate, stearic acid, talc and colloidal anhydrous silica.

80. (New) The process according to claim 47, which is a tablet.

81. (New) The process according to claim 80, wherein the pharmaceutical excipients are at least one filler and at least one lubricant or release agent.

82. (New) The process according to claim 80, comprising

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|---|-----------|----------|
| 1. Roflumilast | 0.125 mg | |
| 2. Lactose monohydrate | 49.660 mg | |
| 3. Corn starch | 13.390 mg | |
| 4. polyvinylpyrrolidone of molecular weight 1,000,000 – 1,500,000 | | 1.300 mg |
| 5. Magnesium stearate (vegetable) | 0.650 mg. | |

83. (New) The process according to claim 80, comprising

- | | | |
|---|-----------|----------|
| 1. Roflumilast | 0.250 mg | |
| 2. Lactose monohydrate | 49.660 mg | |
| 3. Corn starch | 13.390 mg | |
| 4. polyvinylpyrrolidone of molecular weight 1,000,000 – 1,500,000 | | 1.300 mg |
| 5. Magnesium stearate (vegetable) | 0.650 mg. | |

84. (New) The process according to claim 80, comprising

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|---|-----------|----------|
| 1. Roflumilast | 0.500 mg | |
| 2. Lactose monohydrate | 49.660 mg | |
| 3. Corn starch | 13.390 mg | |
| 4. polyvinylpyrrolidone of molecular weight 1,000,000 – 1,500,000 | | 1.300 mg |
| 5. Magnesium stearate (vegetable) | 0.650 mg. | |

85. (New) The process according to claim 47, further comprising producing a solid solution of the PDE 4 inhibitor in the PVP as carrier.

86. (New) The process according to claim 85, wherein the solid solution is a solid

solution with amorphous structure, in which the PDE 4 inhibitor is in the form of a molecular dispersion in the carrier material.

87. (New) The process according to claim 47, wherein said granulating step (b) is conducted in a fluidized bed granulator.